

***United States Court of Appeals
for the Second Circuit***



APPENDIX

75-7143

United States Court of Appeals

For the Second Circuit.

MALACHY J. SMYTH and LUCY SMYTH,
Plaintiffs-Appellants,

vs.

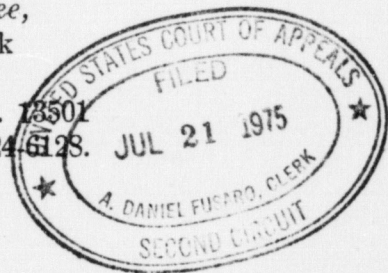
THE UPJOHN COMPANY,
Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK.

APPENDIX TO DEFENDANT-APPELLEE'S BRIEF.

KERNAN AND KERNAN,
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Building,

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1a
EXCERPTS FROM TRANSCRIPT.

1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF NEW YORK

3 - - - - -
4 -
5 - MALACHY J. SMYTH & LUCY SMITH,

6 Plaintiffs,

7 - against -
8 -

9 - THE UPJOHN COMPANY,

10 Defendant.
11 -
12 - - - - -

13 71-CV-412
14

15 The following is a portion of the pro-
16 ceedings held in the United States District Court,
17 Federal Building, Utica, New York, before HONORABLE
18 EDMUND PORT, United States District Judge, and a
19 Jury, commencing on the 20th day of January 1975.
20

21 APPEARANCES:

22 COUPE, COUPE & MATT, ESQS.

23 LEO COUPE, ESQ.

24 Of Counsel

25 Attorneys for Plaintiffs

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Of Counsel

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Utica, New York

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1 THE COURT: All right, Mr. Coupe.

2 MR. COUPE: Your Honor, I would like to call
3 the plaintiff, Mr. Malachy Smith.

4 MALACHY J. SMYTH

5 called as a witness in his own behalf, being first duly
6 sworn was examined and testified as follows:

7 DIRECT EXAMINATION

8 BY MR. COUPE:

9 Q Dr. Smith, you are the plaintiffs in this action,
10 are you not?

11 A Yes.

12 Q Where do you live?

13 A Utica, New York.

14 Q And are you a practicing physician and surgeon
15 licensed under the laws of the State of New York?

16 A Yes I am.

17 Q And how long have you been so?

18 A Altogether you mean? About 22 years.

19 Q Licensed under the laws of the State of New York?

20 A No, since 1965.

21 Q All right, and prior to that time you were licensed
22 to practice medicine where?

23 A In England, Ireland, Canada.

24 Q Now Dr. Smith, to go back, can you tell us where
25 you were born?

1 A In Ireland.

2 Q What year?

3 A 1914.

4 Q And did you receive any medical training in Ireland?

5 A Yes, in Dublin.

6 Q And did you receive any medical training in England?

7 A Yes, in Edinburgh, Scotland, and London, England.

8 Q And did you during this period of time decide to
9 engage in a specialty?

10 A Yes, after the war, after serving in the Royal Air-
11 force during the war I took up the specialty of
12 orthopedics.

13 Q And orthopedics, if you will please define it for
14 us.

15 A It is a surgeon specialty who deals in the treat-
16 ment of deformities, bone and joint surgery, fract-
17 ures, congenital deformities.

18 Q In other words, you are a bone surgeon, is that
19 correct?

20 A Yes.

21 Q Now during the period that you serve in the RAF,
22 where did you serve?

23 A England, Middle East, Italy.

24 Q Whereabouts in the Middle East?

25 A The desert, Western Desert, Cairo.

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1 Q And near the Suez Canal.

2 A Near the Suez Canal, yes.

3 Q During this period of time, did you ever have any
4 illness?

5 A No.

6 Q And --

7 THE COURT: Doctor, you served as a physician
8 in the RAF?

9 THE WITNESS: Yes, as a physician.

10 BY MR. COUPE:

11 Q And at the time you were discharged from the RAF,
12 what sort of a discharge did you receive?

13 A A normal discharge.

14 Q There was no medical discharge?

15 A No medical discharge.

16 Q Now after you were discharged from the RAF, where
17 did you go to work?

18 A I took up training in the Royal College of Surgeons,
19 in Edinburgh, Scotland.

20 Q How long were you there?

21 A About, I think, it was 5 or 6 years.

22 Q And as a result of this study, did you receive any
23 kind of degree or recognition in your profession?

24 A Yes, I became a Fellow of the Royal College of
25 Surgeons by examination.

1 Q A Fellow of the Royal Surgical College of Surgeons,
2 that is the English College of Surgeons, is it?

3 A Yes.

4 Q And were you again specializing in orthopedic surg-
5 ery?

6 A Yes, strictly, entirely then orthopedics.

7 Q Did there come a time when you practiced orthopedics
8 in the city of London?

9 A Yes, I went from Edinburgh to London.

10 Q What hospital in London did you practice in?

11 A Saint Giles Hospital.

12 Q When did you leave Saint Giles Hospital?

13 A I can't remember that to the year.

14 Q Approximately after how long?

15 A After about a year and a half or two years in London.

16 Q Where did you go from Saint Giles?

17 A To Liverpool.

18 Q Did there come a time when you went to Leeds?

19 A Yes.

20 Q Did you do any teaching at Leeds Hospital?

21 A Well, I was a Senior Fellow in the Teaching Hospital,
22 University Hospital at Leeds, I did some teaching,
23 some research work.

24 Q Now there came a time, did there not, when you left
25 England for this country?

1 A Yes.

2 Q When was that?

3 A That was 1960.

4 Q Where did you go when you left England?

5 A Toronto, Canada.

6 Q And were you employed in any type of medical work
7 in Toronto, Canada?

8 A I was a clinical research fellow for the Workmen's
9 Compensation Board, in conjunction with a teaching
10 hospital in Toronto.

11 Q What hospital was that?

12 A Toronto General Hospital.

13 Q Now did there come a time when you left Canada?

14 A Yes.

15 Q What year was that?

16 A That was '61, I think.

17 Q Where did you go?

18 A Came down to Clifton Springs, New York.

19 Q Where is Clifton Springs in relation to Utica?

20 A It is about 35 to 40 miles from Utica, 40 miles
21 from Utica.

22 Q Between Utica and Syracuse?

23 A Well, it is a bit more, it is west of Syracuse, it
24 is south of Rochester, it is a bit more, I should
25 think it is about 60 miles.

1 Q Well, would it be near Rochester?

2 A Yes, south of Rochester.

3 Q How far south of Rochester?

4 A It is 35 miles, approximate, south of Rochester.

5 THE COURT: Near Newark, New York, isn't
6 it?

7 THE WITNESS: Yes, near Newark.

8 BY MR. COUPE:

9 Q How long did you stay at Clifton Springs?

10 A Until 1965, '66.

11 Q And while you were at Clifton Springs, what sort
12 of work did you do?

13 A I was Chief of Orthopedic Surgery there.

14 Q Were you doing operating at that time?

15 A Yes.

16 Q Now did there come a time when you were in Clifton
17 Springs that you came in contact with a drug called
18 Lincocin?

19 A Yes.

20 Q And did you use it in the course of your surgery in
21 Clifton Springs?

22 A Yes I did.

23 Q Were there any bad results as a result of your us-
24 ing Lincocin when you were practicing in Clifton
25 Springs?

1 A Not in my experience.

2 Q After you left Clifton Springs, where did you come?

3 A Came to Utica.

4 Q And that was what year?

5 A That was '66.

6 Q Now prior to your coming to Utica in 1966, had you
7 ever suffered from any trouble with the large bowel
8 or the colon during anytime in your life?

9 A No.

10 Q When you came to Utica, did you become associated
11 with a hospital?

12 A Yes, I got on the staff of all the Utica hospitals,
13 Saint Lukes, Faxton, Saint Elizabeths.

14 Q And you continued to practice your profession of
15 orthopedic surgery?

16 A Yes.

17 Q Did you practice in Utica in any other -- or in this
18 area, I should say, in any other hospitals than the
19 ones you have just mentioned?

20 A Well, for a while I was at Marcy Hospital, I was
21 the orthopedic surgeon at Marcy.

22 Q Marcy Hospital is a state facility in Marcy, New
23 York, for the mentally ill, is that correct?

24 A Yes.

25 Q And did you also have a private practice?

1 BY MR. COUPE:

2 Q Now after you came to the city of Utica, Doctor, did
3 you also perform operations, I presume, is that cor-
4 rect?

5 A Yes.

6 Q And during the course of the performing of these
7 operations, had you the need to guard against bone
8 infection?

9 A Yes.

10 Q Because your operations were primarily concerned
11 with bones, weren't they?

12 A Yes, bones and joints.

13 Q And when the bone became open either through trauma,
14 an accident or something of that sort so that it
15 might be fractured or because it was necessary to
16 perform surgery upon that bone, was it necessary
17 for you to guard against infection?

18 A Yes, we took extreme precautions in this particular
19 kind of surgery.

20 Q Now did you use a particular drug of choice in
21 guarding against these infections?

22 A Yes.

23 Q What was the name of that drug?

24 A I used Lincocin.

25 Q Now, Doctor, approximately how many times had you

1 used Lincocin on your patients prior to February 3
2 of 1970?

3 A I would think 40 or 50 times.

4 Q And had you any bad results?

5 A No.

6 Q With Lincocin?

7 A No.

8 Q There had been no adverse reactions, is that correct?

9 A No.

10 Q Doctor, had you had occasion to take this drug your-
11 self before February 3, 1970?

12 A Yes.

13 Q And can you tell us when that was?

14 A Approximately in 1967.

15 Q And can you tell us the occasion?

16 A I can't exactly, no.

17 Q Did it have to do --

18 MR. HUNT: I have a little trouble --

19 THE COURT: Doctor, will you try to keep
20 your voice up, it is necessary that the jury hear
21 your testimony and that Mr. Hunt hears you to your
22 right.

23 THE WITNESS: All right.

24 BY MR. COUPE:

25 Q Doctor, can you tell us whether it had anything to

1 do with an infected tooth?

2 A Oh yes, that's right, I forgot about that, I had an
3 infected tooth.

4 Q And for how many days did you take Lincocin?

5 A I think 3 or 4 days.

6 Q Did you have any adverse reactions yourself?

7 A No, none.

8 Q Now during the early part -- let me withdraw that,
9 please. When you first consulted me, Doctor, do
10 you recall where it was?

11 A Saint Elizabeth's Hospital.

12 Q And this was sometime during the spring of 1970,
13 is that correct?

14 A Yes.

15 MR. HUNT: Excuse me. Your Honor, I
16 would object to leading questions, I think that --

17 THE COURT: All right, the form of the
18 objection is sustained. Avoid leading the witness.

19 MR. COUPE: All right, Your Honor.

20 BY MR. COUPE:

21 Q Will you tell the court and the jury the circumstan-
22 ces of my interview with you?

23 A I was in the hospital suffering from colitis and I
24 consulted you about it.

25 Q Now do you recall talking about the dates on which

1 you took the Lincocin?

2 A Yes, I do.

3 Q Do you recall what dates you told me at that time?

4 A February 3.

5 Q Was there any discussion of any January dates at
6 that time?

7 A No, I don't think so.

8 THE COURT: What did you say, Doctor, you
9 were hospitalized at that time for what?

10 THE WITNESS: For a condition called
11 colitis.

12 BY MR. COUPE:

13 Q Now prior to February 3, 1970, did there come a
14 time when you suffered from a particular ailment?

15 A Yes, I had the flu and I developed sinusitis.

16 MR. HUNT: Your Honor, would it be per-
17 missible for me to move over this way a little bit?

18 THE COURT: Yes, as a matter of fact, you
19 may sit in one of those chairs along the inside
20 rail.

21 MR. HUNT: I have a little difficulty
22 understanding some of the answers.

23 THE COURT: What we will do, the Clerk
24 tells me that he will rearrange the court room
25 tomorrow so that both tables will be nearer the

1 jury and nearer the witness.

2 MR. HUNT: Fine.

3 MR. COUPE: That will be very helpful.

4 THE COURT: It hardly pays to do it to-
5 night.

6 MR. COUPE: Right.

7 MR. HUNT: Your Honor, would it be permis-
8 sible for me to hear that last answer?

9 (The Reporter read back the last question
10 and answer as above recorded.)

11 BY MR. COUPE:

12 Q Will you describe what that is?

13 A That is an inflammation and infection of one of the
14 sinuses of the head.

15 Q In this instance, which sinuses of the head in your
16 case were affected?

17 A The frontal sinuses.

18 Q Can you indicate with your fingers to the jury where
19 those sinuses are located?

20 A Right at the top of the nose, on each side of the
21 nose (indicating).

22 Q You are indicating over your eyebrow, just on either
23 side of the bridge of your nose?

24 A Yes, right there (indicating).

25 Q Will you describe the feeling you had as a result

1 jury. You are not to infer anything or speculate
2 concerning what the court might be inferring by
3 reason of the questions that I ask, because I don't
4 mean to infer anything except to obtain information.

5 BY MR. COUPE:

6 Q Now, Doctor, I believe you testified that this had
7 interfered with your surgery and that you were con-
8 cerned about infecting patients.

9 A Yes.

10 Q Did you then come to a conclusion as to what treat-
11 ment you should give yourself?

12 A Yes, I did.

13 Q And what conclusion did you come to?

14 A That I would take Lincocin.

15 Q And did you do so?

16 A I did so.

17 Q On what date did you take it?

18 A On February 3.

19 Q What was the dosage that you took on February 3?

20 A Five hundred milligrams.

21 Q How many times a day did you take it?

22 A Twice a day.

23 Q And at what times of the day did you take it?

24 A Morning and evening.

25 Q Now you took it on the 4th as well as the 3rd?

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1 A Yes.

2 Q That is the two doses on each day?

3 A Yes.

4 Q The same number of milligrams?

5 A Yes.

6 Q Now 500 milligrams, is that the prescribed dose set
7 forth in the package insert and the Physician's
8 Desk Reference?

9 A Yes, it is.

10 Q By the Upjohn Company?

11 A Yes, it is.

12 MR. HUNT: I take it you are referring
13 as of the date the Doctor took it?

14 MR. COUPE: Oh, yes.

15 BY MR. COUPE:

16 Q And at the end of the 4th did you notice anything
17 unusual about your condition?

18 A Well, I began to get diarrhea.

19 Q Now when you say diarrhea, will you describe it in
20 more detail for us? We are referring to the 4th of
21 February.

22 A That means a loose stool and the bowel acting much
23 too frequently, perhaps four or five times a day,
24 maybe at night as well.

25 Q Now I am talking about the 4th of February, can you

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1 tell me how often a day you had a bowel movement
2 on the 4th of February?

3 A I think three or four times.

4 Q Now did you continue to take the drug?

5 A Yes, I did.

6 Q Did you take it in a different form?

7 A Yes, I changed to the injectable form.

8 Q How many milligrams of the injectable form did you
9 take?

10 A Six hundred milligrams.

11 Q How many times on the 5th did you take 600 milli-
12 grams of the injectable form?

13 A Once a day.

14 Q Did you do the same on the 6th?

15 A Yes.

16 Q Now on the 6th did you notice anything about your
17 body?

18 A About my body?

19 Q Yes.

20 A Well, I was having diarrhea.

21 Q Well, compared to the 4th, what was it like?

22 MR. HUNT: I object to the form of the
23 question. I think counsel should let the doctor
24 describe the course rather than making comparisons.

25 THE COURT: All right, tell us, Doctor,

1 as best you can, describe the nature of what occur-
2 red on what, is it the 6th that you are interested
3 in now?

4 MR. COUPE: Yes, Your Honor.

5 THE COURT: All right, the 6th.

6 THE WITNESS: I didn't feel too well and
7 I had a little blood perhaps in the diarrhea.

8 BY MR. COUPE:

9 Q How many times a time did you have a bowel movement
10 on the 6th?

11 A It was much more, I would say 5 or 6 or 7 times.

12 Q And what did you do about the drug on the 6th?

13 A I stopped taking it.

14 Q Did you take any other drug on the 6th?

15 A No.

16 Q Now following that will you tell us what happened
17 for the next week?

18 A Well, I continued to have diarrhea, I took something
19 for it to try to stop it, control it.

20 Q What did you take?

21 A I took a little tincture of belladonna, Parepectolin,
22 I had a little paregoric, too, I think.

23 MR. HUNT: Excuse me, Your Honor, the
24 doctor went a little bit rapidly, I would like to
25 make notes on that if I could.

1 MR. COUPE: Very good, Your Honor.

2 BY MR. COUPE:

3 Q Now did there come a time when you had some diffi-
4 culty with your throat?

5 A Yes.

6 Q Will you describe that for the jury and tell us
7 about when you noticed that?

8 A That was about probably the Monday after the 6th
9 of February, I gradually got a sore throat and I
10 became aware that this was almost like a fungus
11 infection in my throat which is associated with tak-
12 ing an antibiotic. On the 16th, this was proved,
13 I did in actual fact have a fungus infection of my
14 throat due to a specific fungus associated with
15 taking antibiotics, in this case, Lincocin.

16 Q Where was the culture performed?

17 A This culture was performed at Faxton Hospital.

18 Q Now as a result of this culture, you received a
19 report from the hospital?

20 A Yes.

21 Q What did that report say?

22 A That report said that I had --

23 MR. HUNT: Excuse me. I think the report
24 would be the best evidence, Your Honor.

25 THE COURT: Well, I will let the Doctor

1 testify. You were also your own attending physician
2 at this point, were you not?

3 THE WITNESS: Yes.

4 THE COURT: All right, you may testify.

5 THE WITNESS: The report stated in effect
6 that I had a fungus infection due to a specific
7 fungus called monilial, which was the name of the
8 fungus.

9 BY MR. COUPE:

10 Q After you discovered this, did you take any medica-
11 tion for monilial?

12 A Yes, I took the specific treatment which was Mycos-
13 tatin.

14 Q Do you recall the dosage that you took?

15 A I took a 500,000 unit.

16 Q How many times a day?

17 A Three times a day.

18 Q Did you continue taking this dosage?

19 A Yes.

20 Q For how long?

21 A This went on from the time I started until I think
22 the time I was in the hospital, I did not stop.

23 Q Now did there come a time in February when you left
24 the city of Utica?

25 A Yes.

1 Q Where did you go?

2 A I went to Atlanta, Georgia.

3 Q Now at that time will you describe what your phys-
4 cal condition was, please.

5 A I had a very sore throat, I had not been able to
6 swallow or able to eat, difficulty in drinking, I
7 was still on treatment for the fungus infection, I
8 was weak and I had some diarrhea.

9 Q Will you describe what type of diarrhea you had at
10 this time.

11 A Well, I was having diarrhea which was gradually
12 getting worse, perhaps a bowel movement seven or
13 eight times a day. I had to get up at night.

14 Q And how long did this convention in Atlanta last?

15 A This lasted three days.

16 MR. HUNT: Excuse me, I couldn't hear
17 that.

18 THE WITNESS: It lasted three days, approx-
19 imately, approximately three days, maybe four, three
20 to four days.

21 BY MR. COUPE:

22 Q Were you able to attend every session of the con-
23 vention?

24 A Not every, I was getting worse. I attended some,
25 haphazard kind of way.

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- 1 Q After Atlanta, where did you go?
- 2 A I went to Florida.
- 3 Q What part of Florida?
- 4 A Clearwater.
- 5 Q And will you describe for us please your physical
6 condition while you were in Clearwater?
- 7 A Well, I was worse, I had more diarrhea, I was weak-
8 er than I had been, not able to eat, I had no appe-
9 tite and I was vomiting at times.
- 10 Q Did you lose any weight?
- 11 A Yes, I had lost a lot of weight.
- 12 Q Do you know approximately how many pounds of weight
13 you had lost at the time you were in Clearwater?
- 14 A I would say about 15 pounds or 20 pounds then.
- 15 Q All right, now did there come a time when you were
16 in Clearwater that you had an unusual attack of
17 diarrhea?
- 18 A After my third day in Florida, that night I had an
19 accute hemorrhage from the bowel.
- 20 Q Will you describe for us in layman's terms what
21 happened, what you saw?
- 22 A Well, in the water in the toilet it was full of
23 blood and it was lined with parts of the lining
24 member of the bowel which had been sluffed off,
25 burnt off like.

- 1 Q What do you call that lining of the bowel?
- 2 A That is the mucous membrane.
- 3 Q Would that be something that would float on top of
- 4 the water?
- 5 A Yes, it is like oil and silk in appearance.
- 6 Q And in what way did that cover the surface, was it
- 7 partially covered?
- 8 A It completely covered over a broad bowl of water,
- 9 broad toilet bowl.
- 10 Q At that time did you seek any medical assistance?
- 11 A That day I went to a hospital in Florida, in Clear-
- 12 water.
- 13 Q Do you recall the name of the hospital?
- 14 A That was the Morton Plant Hospital.
- 15 Q What doctor did you see at that hospital?
- 16 A I saw the gastroenterologist, he was a doctor
- 17 called Hirschfeld.
- 18 Q Did you have a conversation with him?
- 19 A I had a conversation with him.
- 20 Q What did he say to you and what did you say to him?
- 21 A Well, I told him about my problem. He was purely
- 22 concerned then with --
- 23 Q (Interrupting) No, not his conclusions, just what
- 24 he said to you and what you said to him.
- 25 A I consulted him about my throat because I was still

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1 concerned about my throat. I was not aware there
2 was anything seriously the matter with my bowel
3 even then.

4 Q You just testified that you had a very serious
5 bowel movement the night before?

6 A Yes.

7 Q You described that to him?

8 A Yes.

9 Q And did you ask his advice about that?

10 A I asked his advice about that.

11 Q And what did he tell you to do?

12 A He told me to get back to Utica.

13 Q And did you do so?

14 A I did so.

15 Q Do you recall the date that you left Clearwater?

16 A We left Clearwater on the tenth.

17 Q Were you able --

18 A (Interrupting) Of March.

19 Q All right.

20 THE COURT: Of March?

21 THE WITNESS: Of March.

22 BY MR. COUPE:

23 Q And where did you go from Clearwater?

24 A We couldn't get back right away, so we got to Tampa

25 We stayed the night in Tampa and flew from there up

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1 to Utica.

2 Q Now during this time will you describe your condi-
3 tion, that is, as far as your strength was concerned.

4 A I was extremely weak.

5 Q Were you able to carry your baggage?

6 A I was not able to carry my baggage.

7 Q Who carried your baggage?

8 A Mainly my wife.

9 Q Then you arrived back in Utica, is that correct?

10 A Yes.

11 Q And at that time what did you do?

12 A I went to bed, I was completely exhausted.

13 Q And how long did you stay in bed?

14 A I stayed in bed for the next six or seven days.

15 Q Did you prescribe any medicine for yourself at that
16 time?

17 A I continued taking the Mycostatin which I thought
18 was my major problem, I was not aware that my bowel
19 had been damaged really by the Lincocin, I was con-
20 cerned with the fungus infection.

21 Q I understand that. Did there come a time when you
22 consulted Dr. Paul Dwyer?

23 A Yes, on the 19th of March.

24 Q Where did you see Dr. Dwyer?

25 A At his office, which is nextdoor to mine.

1 Q Is it correct, Doctor, that you rent office space
2 from Dr. Dwyer in his building?

3 A Yes.

4 Q His office his across the hall?

5 A yes.

6 Q And what conversation took place between you and
7 Dr. Dwyer?

8 A Very short, he said "You look awful. I will get a
9 bed for you at the hospital."

10 Q And what date did you go to the hospital?

11 A 20th of March.

12 THE COURT: While counsel is looking for
13 something, will you spell this medication for me?

14 THE WITNESS: M-Y-C-O-S-T-A-T-I-N.

15 BY MR. COUPE:

16 Q When you got to St. Elizabeths Hospital, did you
17 receive any particular type of treatment?

18 A Yes, I did. At first I got five or six pints of
19 blood, in fact I got seven pints all tolled while I
20 was there.

21 Q This was in March?

22 A In March.

23 Q Go ahead, what else?

24 A I was put on other medications, I was put on corti-
25 sone and I think they attempted to give me Cortisone

1 enemas, but they did not succeed.

2 Q How long were you in the hospital?

3 A Until the 15th of April.

4 Q At the time you were discharged from St. Elizabeths
5 Hospital, will you describe your condition?

6 A After I was discharged?

7 Q At the time you were discharged.

8 A At the time? Well, I was slightly improved, I was
9 less anemic but I still had a lot of bowel problems,
10 a lot of colicky pain and, still a lot of diarrhea.

11 Q Will you tell us what your condition was in reference
12 to your monillial infection?

13 A That was cleared up completely.

14 Q Now did there come a time, Doctor, when you consult-
15 ed with a doctor in Albany named John Balint?

16 A Yes.

17 Q Do you recall the date that you consulted with Dr.
18 Balint?

19 A It was November 21.

20 Q And will you describe the type of consultation it
21 was, just the facts of the consultation.

22 MR. HUNT: Excuse me, I missed that date.

23 THE WITNESS: November 21.

24 MR. HUNT: 1970?

25 MR. COUPE: Yes.

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1 THE WITNESS: Well, I consulted him about
2 my problem, he had been mentioned to me by friends.

3 BY MR. COUPE:

4 Q Now I don't want anything except the consultation
5 itself.

6 A Well, it was about the diarrhea.

7 Q Yes.

8 A And my loss of weight and my general condition, that
9 I wasn't improving.

10 Q Yes, and what did he recommend that you do?

11 MR. HUNT: Excuse me, is that the consul-
12 tation?

13 BY MR. COUPE:

14 Q Go ahead, Doctor. If there is something more, Mr.
15 Hunt --

16 A (Interrupting) That was it in essence, I consulted
17 him about the fact I had lost about fifty pounds in
18 weight, that I was still having diarrhea, that I
19 was still ill, that I was still weak, and I really
20 wasn't getting what I thought was appropriate treat-
21 ment.

22 Q Now did he advise you to do something on the 21st?

23 A Well, he advised me to have some more x-rays, gas-
24 trointestinal x-rays.

25 Q Where did you have those x-rays taken?

1 THE WITNESS: Yes.

2 (A group of documents marked Plaintiffs'
3 exhibits 1 thru 11-b for identification.)

4 BY MR. COUPE:

5 Q Doctor, I show you Plaintiffs Exhibit 11-b for iden-
6 tification and ask you whether that is the package
7 insert which you read prior to taking Lincocin on
8 the 3rd of February, 1970?

9 A Yes, that is.

10 Q And I show you Exhibit 11 marked for identification
11 and ask you whether this is the copy of the Physic-
12 ian's Desk Reference which you consulted before
13 taking the drug on February 3, 1970?

14 A Yes.

15 Q Now are these both the same insofar as the warning
16 and the adverse reactions sections are concerned?

17 A Yes, they are.

18 Q Now for our benefit, will you explain to us what
19 the first exhibit was, the little piece of paper
20 that I showed you.

21 A That is called a package insert, and there is a
22 little bit of information for the doctor about the
23 drug.

24 Q And where do they find it?

25 A That is found wrapped around the bottle or in the

1 Q Probably from now on during this trial --

2 THE COURT: You will sum up later. I
3 have asked a question. Doctor, PDR stands for
4 Physician's Desk Reference?

5 THE WITNESS: Yes.

6 MR. COUPE: I just wanted to clarify
7 something.

8 THE COURT: It is clarified. Proceed.

9 MR. COUPE: Very well, Your Honor.

10 BY MR. COUPE:

11 Q Under the heading of Lincocin in the Upjohn section
12 of the PDR, did you read the warning which states:
13 "Cases of severe and persistent diarrhea, some with
14 blood and mucous in the stools have been reported
15 and at times have necessitated discontinuance of
16 the drug"?

17 A Yes, I did.

18 Q Did you also read this: "This side effect usually
19 has been associated with oral dosage form but has
20 occasionally been reported following parenteral
21 therapy"?

22 A Yes, I did.

23 Q Now, Doctor, what is parenteral therapy?

24 A That is giving a drug, not the normal way, either
25 into the skin, into the tissues or any other way

1 outside of the stomach.

2 Q And, Doctor, did you also read under a section on
3 the same page which is designated "Adverse reaction:
4 gastrointestinal, glossitis, stomatitis, nausea,
5 vomiting, persistent diarrhea, enterocolitis and
6 pruritis ani"?

7 A Yes.

8 Q Now will you please tell us what glossitis is?

9 A That is an inflammation of the mouth, the tongue.

10 Q And what is stomatitis?

11 A Roughly the same thing.

12 MR. HUNT: Could we go a little bit slow-
13 er?

14 THE COURT: Yes, if you please.

15 THE WITNESS: Glossitis is basically in-
16 flammation of the tongue.

17 MR. HUNT: Tongue?

18 THE WITNESS: Yes, tongue.

19 BY MR. COUPE:

20 Q Stomatitis?

21 A That is inflammation of the mouth, oral cavity.

22 Q Of the mouth?

23 A Of the mouth.

24 Q All right, nausea?

25 A Well, that is a tendency to vomit, you feel sick.

1 Q And vomiting we all know. Persistent diarrhea we
2 know --

3 MR. HUNT: I object to that, I am not
4 sure whether we do know it or not.

5 THE COURT: Well, it doesn't make much
6 difference. I think your question is did the Doctor
7 read it, does that preface --

8 MR. COUPE: Yes, but I wanted him to ex-
9 plain the medical terms.

10 THE COURT: All right, ask him to explain
11 it or if it doesn't require any explanation in your
12 judgment, just ask him whether he read it. But the
13 Doctor is the witness, Mr. Coupe.

14 MR. COUPE: Yes, Your Honor.

15 BY MR. COUPE:

16 Q Enterocolitis, will you describe that for us?

17 A That is an inflammation of the small and large bowels.

18 Q And pruritis ani?

19 A Well, that is an irritation of the exit of the bowel.

20 Q Would it be proper to call it an itching of the
21 rectum?

22 A Yes.

23 THE COURT: Can you identify that by page
24 please?

25 MR. COUPE: Yes, I have, Your Honor, it

1 Q And what is Dr. Balint's specialty?

2 A Dr. Balint specializes again in disease of the colon
3 and of the bowel, and he is a gastroenterologist.

4 Q Gastroenterologist?

5 A Yes.

6 Q He is a professor of gastroenterology, is he?

7 A Yes, I think assistant professor.

8 Q At?

9 A Albany Medical College.

10 Q At Albany Medical College?

11 A Yes.

12 Q Is Dr. Balint the man who cured you?

13 A Well, he certainly set me on the right road, made a
14 tremendous difference.

15 Q Is Dr. Balint in your opinion the physician who has
16 the greatest reputation of all of the doctors whom
17 you have seen in the field of gastroenterology?

18 A Yes, I would think so.

19 Q And the disease colitis, the disease enterocolitis,
20 would all come within Dr. Balint's field, is that
21 correct?

22 A Yes, that's correct.

23 Q And in your opinion, Dr. Balint is the most knowl-
24 edgeable man of all of the people you have seen in
25 the disease that you claim you had, is that correct?

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THE COURT: You can cross examine him.

MR. HUNT: All right.

THE COURT: That may refresh his recollection and it may not.

MR. HUNT: Yes.

THE COURT: You have read it, Doctor?

THE WITNESS: I have read it, yes.

THE COURT: Does that refresh your recollection?

THE WITNESS: I have read it, yes, it does.

THE COURT: All right, now put your direct question if you have one.

BY MR. HUNT:

Q All right. Now let me ask you this, Doctor, you have told us what Dr. Balint told you, is that correct?

A That is correct.

Q Now did you ever pose the question to Dr. Balint: "Doctor" in words of substance, "Doctor, do you relate the taking of the drug Lincocin to my condition?" did you ever pose such a question to Dr. Balint?

A I think I did, yes.

Q And did Dr. Balint give you an answer to that question in writing?

1 A I don't recall.

2 Q You don't recall?

3 A He certainly didn't know it verbally.

4 Q Doctor, you were treated at the Albany Medical Col-
5 lege, is that correct?

6 A Yes.

7 MR. HUNT: May it please the court, I
8 have subpoenaed the record of the Albany Medical
9 College.

10 (Documents marked Defendant's Exhibit C
11 for identification.)

12 MR. HUNT: Your Honor, could I make a
13 short statement of correction? When I have been say-
14 ing in this examination before trial of 1973 a year
15 ago, it occurs to me that would be two years ago.

16 THE COURT: Yes.

17 MR. HUNT: Yes, I would ask to correct
18 that, I lost track.

19 THE COURT: September '73?

20 MR. HUNT: No, the examination before
21 trial I am referring to was in February of '73.

22 THE COURT: I see.

23 MR. HUNT: And I kept referring to it as
24 a year ago. It would be approximately two years ago.

25 THE COURT: All right, I will take judicial

1 Q You say Dr. Balint's notes in the history are in-
2 correct if they state the history of you told him
3 you were doing heavy work?

4 A Yes, heavy work, no heavy work.

5 Q You say his entries are incorrect?

6 A Yes, absolutely.

7 Q Now, Doctor, you told Mr. Coupe that Dr. Balint told
8 you in December of 1970 that you had colitis with
9 ulcerations, is that correct?

10 A Basically correct, yes.

11 Q Is that what you told Mr. Coupe?

12 A Basically, yes.

13 Q Would you look at the records -- you saw Dr. Balint
14 on one occasion in December of 1970, isn't that
15 correct?

16 A Yes.

17 Q And did Dr. Balint put your diagnosis in his records
18 in December of 1970?

19 A Yes, he did.

20 Q Would you read to the jury what Dr. Balint's diag-
21 nosis of your condition was in December of 1970?

22 A Well, he said it was probably Crohn's disease --
23 probably.

24 Q All right.

25 A That is not a diagnosis.

1 Q And you have told us that you are aware that Crohn's
2 disease in your opinion would not come from taking
3 Lincocin, is that correct?

4 A Yes.

5 Q Now, Doctor, you specifically on April 9, 1971 by
6 letter stated to Dr. Balint in words or in effect
7 that you were asking his support in obtaining recom-
8 pense from Upjohn, is that correct?

9 A That is true.

10 Q And recompense means you were asking his aid in
11 getting money from Upjohn?

12 A Recompense for the money I had lost in my practice,
13 I wasn't able to practice.

14 Q And did you pose this question to him in letter
15 form: "I wonder if you could state that I suffered
16 from Lincocin colitis"?

17 A Yes, I did.

18 Q And on April 30, 1971, did Dr. Balint give you a
19 reply in writing to that question?

20 A April 30?

21 Q Yes.

22 A Yes, I have a letter here April 30, 1971.

23 MR. HUNT: May I mark this Defendant's
24 Exhibit C-1, Your Honor?

25 THE COURT: Let the Clerk mark it.

1 MR. COUPE: Is the whole file marked this
2 time?

3 MR. HUNT: Yes.

4 (Documents marked Defendant's Exhibit C-1
5 for identification.)

6 BY MR. HUNT:

7 Q Doctor Smyth, you received the original of this
8 letter of April 30, 1971, did you not?

9 A Yes.

10 Q Have you ever made anyone aware of the contents of
11 that letter, anyone else?

12 A I don't think I did, as far as I know, No, I don't
13 think so.

14 Q Did you destroy the original of that letter?

15 A No, I don't think so.

16 Q Where is the original of that letter?

17 A I don't know, I may have it, I may have it.

18 Q Did you not think that to be an important piece of
19 evidence in your case?

20 A It was a private letter to a private doctor, we
21 were trying to investigate this Lincocin problem.
22 I thought it was a problem letter.

23 Q Did you not think it important enough to give to
24 your counsel, Mr. Coupe?

25 A No, I hadn't thought about it even, it was purely

1 private, I thought, friend to friend.

2 MR. HUNT: I offer in evidence Exhibit
3 C-1.

4 MR. COUPE: I have no objection.

5 THE COURT: Received.

6 (Defendant's Exhibit C-1 for identifica-
7 tion was marked in evidence.)

8 BY MR. HUNT:

9 Q Doctor, as a medical man -- withdraw that. Doctor,
10 in essence, Dr. Balint told you that he had serious
11 doubt as to whether your condition was caused by
12 Lincocin, did he not?

13 MR. COUPE: I would just as soon have
14 the entire letter read.

15 THE COURT: Sustained. The letter is the
16 best evidence. It is in evidence, it may be read
17 to the jury in its entirety.

18 MR. HUNT: Would it be proper to do that
19 at this time, Your Honor?

20 THE COURT: Surely, yes.

21 MR. HUNT: If I may read the letter:

22 "April 30, 1971, Dr. M. J. Smyth, 1611 Genesee
23 Street, Utica, New York 13501 Dear Doctor Smyth:

24 I have now had an opportunity to review
25 the literature concerning the toxicity of Lincocin.

1 As I rather suspected, the review is somewhat uncon-
2 vincing in terms of the production of the type of
3 disease which you had. In all the cases that I have
4 been able to find, the condition was acute and of
5 very short duration.

6 I have some serious doubt as to whether
7 the condition produced was the same as the one from
8 which you suffered. I think it would perhaps be
9 best if we could discuss this matter at sometime
10 when you next come to see me and decide then how to
11 proceed.

12 It is, of course, possible that in your
13 own case the Lincocin was responsible for the pro-
14 duction of the colitis, but its long duration and
15 its radiologic appearances make me suspect that in
16 your instance, this was a coincidence rather than a
17 cause or relationship.

18 When you next come to see me, we can review
19 this matter in more detail.

20 Kindest regards. Sincerely yours, John
21 A. Balint, M.B., M.R.C.P.

22 Professor of Medicine and Head, Division
23 of Gastroenterology"

24 BY MR. HUNT:

25 Q Now, Doctor, after receiving that letter, did you

1 and Mr. Coupe go to Albany again to try to convince
2 Dr. Balint to testify in your behalf?

3 MR. COUPE: Could we have the date?

4 BY MR. HUNT:

5 Q After the letter?

6 A The letter was '71, April of '71.

7 Q After that date did you and Mr. Coupe go to Albany
8 again to try to convince Dr. Balint to testify in
9 your behalf?

10 A It was a long time after that.

11 Q Well, what year would you say?

12 A I think it must have been '73.

13 Q '73, all right, and after that conference in '73
14 you concluded that you would not call Dr. Balint,
15 is that correct?

16 A Well, not immediately, he didn't particularly want
17 to get into any law thing, he was afraid of lawyers.

18 MR. HUNT: You may examine.

19 MR. COUPE: Thank you.

20 REDIRECT EXAMINATION

21 BY MR. COUPE:

22 Q Doctor, there has been a great deal of talk about
23 the Merck's Manual, did you use any other books
24 besides the Merck Manual at the time you were con-
25 cerned about your colitis?

1 Q No, I am --

2 THE COURT: Did you give us a complete
3 diagnosis, your diagnosis?

4 THE WITNESS: He had --

5 THE COURT: No, no, did you --

6 THE WITNESS: I don't understand.

7 THE COURT: You testified to the diagnosis
8 from some records that you have of Dr. Smyth, now
9 is that your complete diagnosis or not?

10 THE WITNESS: Well, Your Honor, I know
11 I put down here diarrhea. Probably diarrhea is
12 more of a symptom than a diagnosis. Diarrhea is
13 a symptom of an irritable bowel, and in that sense
14 I should have written colitis, but I didn't, I wrote
15 just diarrhea.

16 THE COURT: All right.

17 BY MR. COUPE:

18 Q All right, then Doctor, did you make a diagnosis of
19 a colitis?

20 A A colitis was present, yes.

21 MR. HUNT: Well, excuse me, could we have
22 the date of that diagnosis? What date did you diag-
23 nose it?

24 THE COURT: You may have a voir dire at
25 this point.

VOIR DIRE EXAMINATION

BY MR. HUNT:

Q What date did you diagnose colitis, Doctor?

A Well, I have to say that I never wrote the word "colitis," but on his discharge summary from the hospital I used the word diarrhea, which probably is a misnomer in that I used a symptom rather than the word I should have used to cause the symptom.

Q Well, in other words Doctor, what you are saying, nowhere in your records does it ever show you diagnosed colitis in this man?

A I don't think I did use the word colitis.

BY MR. COUPE:

Q In your records only, is that correct?

A In the records.

Q I am asking you today whether at that time you made a diagnosis which you will explain to us today, what was that diagnosis?

A I don't know how you mean it.

Q All right, let me rephrase the question. Doctor, you referred to an x-ray report of Dr. Segal?

A That's right, yes.

Q Now did that x-ray report of Dr. Segal assist you in making a diagnosis?

A Yes, it does.

1 THE COURT: Are you --

2 MR. HUNT: I thought Mr. Coupe said he
3 was finished.

4 THE COURT: Is the examination concluded?

5 MR. COUPE: The examination-in-chief is
6 concluded.

7 THE COURT: All right. Cross examination.
8 I think before you start your cross examination so
9 that you will have an opportunity to examine the
10 notes, we will take a short recess.

11 The jury may step down.

12 (Thereupon a short recess was taken after
13 which the hearing was resumed.)

14 BY MR. HUNT:

15 Q Doctor Dwyer, I am going to pose a hypothetical
16 question to you. Suppose that I as the patient
17 should come to you and give you the following his-
18 tory: that I have a very sore throat, I have had
19 diarrhea for approximately three weeks, I have seen
20 some blood in the passage from my bowels, I have
21 pains in my stomach, I have cramps and I feel terri-
22 ble, and that that has been my condition for basical-
23 ly three weeks, in good medical practice, what would
24 you prescribe, what would you do for such a patient?

25 A Well, I would -- you would have to evaluate the

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1 degree of illness of the patient. A sufficiently
2 ill patient, I would hospitalize the patient.

3 Q All right, we will assume just what I described,
4 that I feel terrible, I have had diarrhea for approx-
5 imately three weeks, that I have pains in my stomach
6 that I have cramps and I have seen blood in the pas-
7 sage from my bowels, assume that to be what I tell
8 you.

9 A Yes.

10 Q You would hospitalize such a patient?

11 A Well, of course you would take a complete history
12 when did the sore throat begin, what relation was
13 the sore throat to the stomach upset.

14 Q Well, suppose you knew that the sore throat may be
15 due to a monilial infection, O.K.?

16 A Yes.

17 Q If you knew that by way of a laboratory test, would
18 you hospitalize the patient?

19 A Yes.

20 Q All right, and with that given set of circumstances
21 would you say that a physician who failed to hos-
22 pitalize such a patient would be guilty of malpractice
23 or in laymen's terms, negligent?

24 A I couldn't make a definite statement on that basis.
25 I don't know how someone else might interpret that.

1 same thing.

2 Q How you would interpret it.

3 A I would interpret it that it would be good medical
4 practice to do so.

5 Q To hospitalize?

6 A Yes.

7 Q And on the contrary, not to do it would be bad medi-
8 cal practice?

9 MR. COUPE: I object to that.

10 BY MR. HUNT:

11 Q I withdraw it. It would be good medical practice
12 to do it?

13 A Yes.

14 Q All right. Now Doctor, what is gastroenteritis?

15 A That would be an inflammatory condition involving
16 the stomach and intestines.

17 Q And when you use intestines, you mean the small
18 intestine and the colon?

19 A Yes.

20 Q All right. In June of 1970, approximately three
21 months after you started treating Dr. Smyth and after
22 you had had an opportunity to see the barium enema
23 that you have testified to and the results of the
24 sigmoidscope, was your diagnosis in the hospital
25 records of this patient gastroenteritis?

1 wrong blank and the clinical diagnosis in the wrong
2 blank, they are reversed, is that right?

3 A That's right.

4 Q All right. What is the clinical diagnosis that
5 appears in the hospital records concerning Dr. Smyth
6 on page six of the hospital records while you were
7 treating him in March and April 1970, will you read
8 the words of the jury?

9 A Enterocolitis.

10 Q Enterocolitis. Doctor, you say that you have con-
11 fused the word diarrhea with colitis, is that cor-
12 rect?

13 A No.

14 Q That you put it down by mistake?

15 A I put diarrhea down, and I said that was a symptom
16 rather than a diagnosis.

17 Q All right. If you saw the words "severe and per-
18 sistent diarrhea with blood and mucous in the
19 stools," as a medical man would that alert you to
20 colitis?

21 A Yes.

22 Q And that is true of any physician with adequate
23 training in your opinion?

24 A I presume he would think that way.

25 Q All right. Enterocolitis involves inflammation or

1 disease of the small intestine and the large bowel,
2 is that correct?

3 A I think that is a correct diagnosis.

4 Q Enteritis concerns just the small intestine and
5 colitis just the large bowel, is that correct?

6 A Yes.

7 Q Which is the more encompassing terms, in other
8 words, if you were going to describe something, what
9 would you describe, what would be the more inclusive
10 term; enterocolitis or enteritis or colitis?

11 A Enterocolitis would involve the large and the small.

12 Q All right, thank you. Doctor, did you receive a
13 letter from Dr. Balint?

14 A Not that I ever recall.

15 Q May I have that exhibit? Doctor Dwyer, I show you
16 Defendant's Exhibit B marked for identification and
17 ask you if you ever saw the original of that?

18 A I don't recall ever seeing the original of it.

19 Q Well, would you read it, Doctor?

20 A The whole letter?

21 Q Well, let me ask you first, have you ever read it
22 before I just handed it to you?

23 A Why Mr. Coupe showed me a copy of this and wondered
24 if I had the original, and I said No, I didn't, I
25 had no remembrance of it.

Dwyer-Recross

1 was an entire GI tract infection, did you not?

2 A With the monilia, yes, the entire tract.

3 Q Which would include the small intestine?

4 A Yes, the entire tract.

5 Q And did you tell me at that time that as of August
6 6, 1973 that it was your opinion that there was no
7 clinical signs of any disease in Dr. Smyth at that
8 time?

9 A No clinical?

10 Q That there were no clinical signs of disease as of
11 the date I talked to you with reference to Dr.

12 Smyth, which was August 6, 1973, that as of that
13 date --

14 A (Interrupting) I don't remember saying that there
15 was no sign, I don't know that actually, whether I
16 did or not.

17 Q Well, your records indicate no clinical signs of
18 disease as of August of '73, isn't that a fact?

19 A I have no records of that, that's right.

20 Q Now I am wondering, did you tell me at that time
21 that Dr. Smyth had taken a dose of Mycostatin
22 before from Faxton Hospital at the time you first
23 saw him?

24 A I wouldn't know that.

25 Q Well, do your records indicate what medication he

1 had before he came to see you?

2 A No.

3 Q Wouldn't that be important to know what medication
4 he had taken before he came to see you or before you
5 met him in the lot?

6 A It would be helpful, but it was an obvious infection
7 that needed treatment, and I don't know whether he
8 had treated it before or not.

9 Q And within a period of three or four days you start-
10 ed to get that infection under control, did you not?

11 A Yes.

12 Q And did it appear obvious to you that the treatment
13 that had been going on before that was obviously
14 inadequate?

15 A I think that was an assumption.

16 Q A fair assumption?

17 A Yes.

18 Q So whatever medical treatment Dr. Smyth had been
19 getting between February 3 and March 20, it is your
20 opinion that the treatment was not in accordance
21 with good medical standards as existed in Oneida
22 County at that time?

23 A Well, they weren't adequate.

24 Q They weren't adequate. If they weren't adequate,
25 they weren't good, is that a fair statement?

1 A You could assume that.

2 MR. HUNT: All right. Fine. That's all,
3 Doctor.

4 REDIRECT EXAMINATION

5 BY MR. COUPE:

6 Q Doctor, there is one thing. Mr. Hunt has referred
7 to in your office records, I believe it was a date
8 November 26.

9 A 25.

10 Q 25, will you indicate what was done on that day?

11 A Doctor Smyth received a small flu vaccine, half a
12 dose, a quarter of a cc.

13 Q Is there any record in there of your having any
14 conversation with him on that day?

15 A No.

16 Q Do you have an office nurse who administers vaccine
17 of that sort?

18 A Yes, she does.

19 Q And in this case can you tell us to the best of your
20 recollection whether that was done by you or by the
21 nurse?

22 A It was done by the nurse.

23 Q Do you have any independent recollection of even
24 talking with Dr. Smyth on that day?

25 A No, I don't.

1 BY MR. HUNT:

2 Q In part?

3 A In part, yes.

4 Q Your answer is yes?

5 A It would be yes.

6 MR. HUNT: All right. That's all.

7 MR. COUPE: That's all, Doctor.

8 (Witness excused.)

9 (Direct and cross examination of Dr.
10 Harold C. Heintz.)

11 A F T E R N O O N S E S S I O N

12 MR. COUPE: I would like to call Dr.
13 Robert B. Wallace.

14 DR. ROBERT B. WALLACE,
15 called as a witness in behalf of the plaintiff
16 being first duly sworn was examined and testified
17 as follows:

18 DIRECT EXAMINATION

19 BY MR. COUPE:

20 Q Dr. Wallace, do you reside?

21 A 28 Tennyson Road, New Hartford.

22 Q What is your profession?

23 A Physician.

24 Q Are you duly licensed to practice under the laws of
25 the State of New York?

1 A Yes I am.

2 Q And do you have a specialty?

3 A Internal medicine.

4 Q Do you have a sub-specialty?

5 A Gastroneurology.

6 Q Can you tell us about your formal education.

7 A Under-graduate education Cornell University, Cornell
8 University Medical College, graduated in 1947. I
9 interned at Lenoxville Hospital, New York. I took
10 three years of residency in Jersey City Medical
11 Center in Jersey City and left there in 1951 and
12 spent approximately two years in the Air Force as
13 a medical officer doing internal medicine in a
14 hospital in Japan, and I spent one more year at
15 Henry Ford Hospital, Detroit, in gastroneurology
16 before coming here in August of 1954.

17 Q Are you associated with any clinic or group of
18 practitioners in the city of Utica?

19 A Partner in Slocum Dixon Medical Group.

20 Q Now Doctor, did you have an opportunity to examine--
21 let me show you Exhibits 16 to 65.

22 A Yes, I reviewed those reports.

23 Q And can you tell us what those reports are please?

24 A Those reports are a series of patients who had had
25 Lincomycin and had developed gastrointestinal

1 symptoms as a result. Most of the gastrointestinal
2 symptoms were inflammatory disease of the colon.

3 MR. HUNT: I think you just asked him to
4 identify what they are.

5 MR. COUPE: I did.

6 MR. HUNT: Not describe them.

7 BY MR. COUPE:

8 Q Now were all of these reports -- first of all, Mr.
9 Hunt, at this time would you stipulate that these
10 are reports which were furnished us by the Upjohn
11 Company from its files, that they are photocopies
12 of the reports which are in the Upjohn file and that
13 they are kept in the regular course of business by
14 the Upjohn Company?

15 MR. HUNT: Well, I will stipulate that we
16 did furnish you said reports, but I have not had
17 the opportunity to examine those.

18 MR. COUPE: I am sorry, let me have you
19 examine them.

20 MR. HUNT: Well, I will accept them. Does
21 counsel represent that those are the reports which
22 we furnished of adverse reactions prior to --

23 MR. COUPE: They are those reports of ad-
24 verse reactions which have to do with colitis. Other
25 reports were furnished which are not material prior

1 section after Lisacoin is as follows -- now it is
2 a long section, you want me to read it?

3 BY MR. COUPE:

4 Q I just want you to read what is pertinent to this
5 case.

6 A O.K.: "Warning. Cases of severe and persistent
7 diarrhea, some with blood and mucous in the stools,
8 have been reported, and at times have necessitated
9 discontinuance of the drug," and that is in italics.
10 "The side effects usually has been associated with
11 oral dosage form but has occasionally been reported
12 following parenteral therapy."

13 Q Now, Doctor, as a physician, practicing physician,
14 a specialist in internal medicine with a sub-
15 specialty of gastroenterology, do you have an opin-
16 ion as to whether that warning is sufficient to the
17 medical profession as a whole in view of the adverse
18 reaction reports which you have just testified to?

19 MR. HUNT: Object to that on the grounds
20 there is no proper foundation.

21 THE COURT: I will let him answer.

22 MR. HUNT: Could I have a preliminary
23 examination?

24 THE COURT: Yes, you may have a voir dire.

25 VOIR DIRE EXAMINATION

1 BY MR. HUNT:

2 Q Doctor, do you know how that warning is arrived at?

3 A No.

4 Q Do you know whether the manner in which that warn-
5 ing is published, whether it is subject to regula-
6 tion by the United States of America, the Federal
7 Drug Administration?

8 A No, I don't.

9 Q And would it not be necessary before rendering an
10 opinion in this respect to know what the law is
11 with regard to the publication of such material?

12 A Well, I can't quite answer yes or no on that. In
13 that regard, I suppose it would help if I knew what
14 the law was, but we are subject, of course, to pre-
15 scribing medication.

16 Q Let me ask you this, Doctor, you are testifying as
17 to what appears in the Physician's Desk Reference?

18 A Right.

19 Q Is that correct.

20 A Yes.

21 Q Do you know whether there are laws regulating what
22 is written in the Physicians Desk Reference?

23 A Well, the FDA has something to do with it, I am
24 sure of that, so there must be some laws that con-
25 trol it somehow.

1 MR. COUPE: Could I approach the bench?

2 THE COURT: Yes.

3 (The following proceedings took place at
4 the bench out of the hearing of the jury.)

5 MR. COUPE: The only thing this doctor is
6 going to testify to as an ordinary physician is
7 is this enough warning to him so that he would hesi-
8 tate to prescribe this drug.

9 THE COURT: Under what conditions?

10 MR. COUPE: Under the conditions that he
11 is seeing in these adverse reaction reports. No
12 matter what the government has to do with it, would
13 the physician prescribe the drug, I don't know.

14 THE COURT: It seems to me that your
15 question would be better if it were framed in the
16 context of "good medical practice."

17 MR. COUPE: All right, I will do that.

18 THE COURT: And although there is a very
19 recent case in the Circuit that permits an opinion
20 to go so far as to answer the ultimate question to
21 be determined by a jury, I was very much surprised,
22 and I am sure I have it in my notebook, but I think
23 it is better --

24 MR. HUNT: May I continue my voir dire?

25 THE COURT: Yes.

1 MR. COUPE: That is what I am objecting
2 to, this type of voir dire. It can be brought out
3 in cross examination.

4 (The following proceedings took place in
5 the presence and hearing of the jury.)

6 VOIR DIRE CONTINUED

7 BY MR. HUNT:

8 Q Doctor, do I understand that what you are about to
9 give an opinion about is whether what is stated in
10 the 1970 PDR in your opinion was in accordance with
11 good medical practice?

12 A I was going to make the statement, I didn't.

13 Q Is that what you were --

14 A (Interrupting) Yes.

15 Q All right. Now are you aware -- have you seen the
16 package insert for the year it was used in the year
17 1969 and early 1970?

18 A No. (Exhibit handed to witness.)

19 MR. HUNT: Your Honor, may Mr. Coupe
20 stipulate the wording in the package insert is the
21 same as in the Physicians Desk Reference.

22 THE COURT: We have testimony to this
23 effect; that it is no part --

24 THE WITNESS: This looks to be the same.

25 BY MR. HUNT:

1 Q Well, Doctor you used the Physicians Desk Reference.
2 do you?

3 A Yes.

4 Q And I am going to ask you to assume that the mater-
5 ial contained in the Physicians Desk Reference is
6 the same material that is contained in the current--
7 in the package insert for the corresponding year?

8 A Right.

9 Q Are you aware of whether the Government of the
10 United States regulates what is put in the package
11 insert?

12 A I suspect that may be, I am not positive.

13 Q All right.

14 THE COURT: If you don't know, just say
15 you don't know.

16 THE WITNESS: All right, I don't know.

17 BY MR. COUPE:

18 Q Would you not agree that before expressing an opin-
19 ion as to what should be contained in a Physicians
20 Desk Reference or in a package insert, it would be
21 incumbent upon you to know what the law is regard-
22 ing the publication and issuance of those documents?

23 A Yes.

24 Q And you have no knowledge as to the law?

25 A I have no knowledge.

1 MR. HUNT: Your Honor, I would object to
2 any question along these lines in view of the
3 Doctor's answers.

4 THE COURT: If he says he can form an
5 opinion, has an opinion. He hasn't answered that
6 yet, I don't think, but let's find out first whether
7 he has an opinion.

8 BY MR. COUPE:

9 Q All right, Doctor, let me ask the question again,
10 based upon the adverse reaction reports which you
11 read, all of which were in existence prior to 1970,
12 and upon good medical practice and upon your experi-
13 ence as an internist with a sub-specialty in gastro-
14 enterology, have you an opinion as to whether or
15 not that was sufficient warning to the medical pro-
16 fession as a whole of the disease acute colitis?

17 A I don't think the warning is sufficient.

18 MR. HUNT: Excuse me just a minute --

19 THE COURT: Just whether or not you have
20 an opinion with reasonable medical certainty.

21 MR. HUNT: Your Honor, I would just simply
22 like on that question to render my objection that
23 there is no foundation that has been laid by which
24 the Doctor can express that opinion.

25 THE COURT: I think the Doctor has set out

1 his qualifications with sufficient detail. Over-
2 ruled.

3 BY MR. COUPE:

4 Q Do you have an opinion, Doctor?

5 A I have an opinion that that is not sufficient.

6 Q All right. Now Doctor --

7 THE COURT: That is, Doctor, as I under-
8 stand your answer and the question, the question was
9 rather long, but you are now giving an opinion as
10 to what is good medical practice, is that right?

11 THE WITNESS: I would agree to that.

12 BY MR. COUPE:

13 Q Doctor, I show you supplement C of 1970 to the
14 same Physicians Desk Reference and ask you to read
15 the warning section --

16 (The following proceedings have been
17 transcribed separately.)

18 MR. HUNT: Are you through with the wit-
19 ness, Mr. Coupe?

20 MR. COUPE: Yes, go ahead.

21 THE COURT: Cross examination.

22 CROSS EXAMINATION

23 BY MR. HUNT:

24 Q Doctor, when were you retained to give expert test-
25 imony in this case?

1 A Sunday.

2 Q And you have given an opinion -- did you look at the
3 section "adverse reactions" in your PDR?

4 A Yes.

5 Q Did you see the word "enterocolitis"?

6 A Yes.

7 Q What is enterocolitis?

8 A Enterocolitis is an inflammation of the small and
9 large intestine.

10 Q And colitis is an inflammation of the --

11 A (Interrupting) Large intestine.

12 Q And enterocolitis is a more encompassing term, is
13 that correct?

14 A Yes, it may be vague.

15 Q Is it in the medical dictionary?

16 A Yes.

17 Q What medical dictionary to you subscribe is the out-
18 standing medical dictionary?

19 A The one that comes to mind is "Stedman's."

20 Q Are you familiar with Dr. Lands?

21 A Not right off hand.

22 Q Have you looked at Stedman's before coming here to
23 testify?

24 A No.

25 Q Well, is the standard definition of enterocolitis

1 A Yes, or acute means it is of recent onset.

2 Q Recent onset?

3 A Yes.

4 Q Doctor, what is a persistent diarrhea with blood
5 and mucous in the stools, what does that mean to a
6 physician?

7 A By and large acute colitis, acute ulcerative colitis.

8 Q That is indicative of acute colitis or ulcerative
9 colitis?

10 A Yes.

11 Q That is what that would mean if you read those
12 words, is that right?

13 A That is true.

14 Q And this warning did say "cases of severe and per-
15 sistent diarrhea, some with blood and mucous in the
16 stools have been reported," and to a physician that
17 would paint a red flag as to the possibility of
18 colitis, isn't that a fact?

19 A That could be true.

20 Q Well, it would be true, wouldn't it, Doctor?

21 A Yes.

22 MR. HUNT: All right. That's all.

23 REDIRECT EXAMINATION

24 BY MR. COUPE:

25 Q Doctor, in the adverse reaction report in the

1 Q And you are aware that the Federal Drug Administra-
2 tion of the United States regulates what is put in
3 the package insert and regulates which is put in
4 the Physicians Desk Reference, are you not?

5 A They are suppose to, yes.

6 Q And you are aware that that includes the language
7 as to what is put in the package insert in the
8 Physicians Desk Reference, that that is regulated
9 by the United States Government, you are aware of
10 that, are you not?

11 A Yes, I think so.

12 MR. HUNT: That's all.

13 MR. COUPE: That's all, Doctor.

14 (Witness excused.)

15 * * *

16
17 This is to certify that the foregoing
18 record is a true and accurate transcript of a
19 portion of the proceedings taken at the time and
20 place noted in the heading hereof.

21 *Martha L. Miller*
22 Official Court Reporter
23 United States District Court
24 Northern District of New York
25

